Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0242239	08/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ecu Health Multispecialty Clinic	101 Clinic Drive, Tarboro, NC	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of 2019, 2020, 2021, and 2022 quality control and maintenance records, review of 2020, 2021, and 2022 American Proficiency Institute (API) proficiency testing records, interview with the general supervisor (GS) 8/16/22 and telephone interview with API representative 8/17/22, the laboratory failed to enroll in proficiency testing for coagulation testing in 2022. Review of 2019, 2020, 2021, and 2022 quality control and maintenance records revealed the laboratory discontinued patient testing for prothrombin time (PT) and partial thromboplastin time (PTT) in November 2019. The laboratory resumed patient PT and PTT testing in October 2021. Review of 2020, 2021, and 2022 API proficiency testing records revealed the laboratory did not participate in proficiency testing for PT or PTT during 2020, 2021, or the first event of 2022. During interview at approximately 4:50 p.m., the GS stated that the laboratory's 2022 proficiency testing enrollment for PT and PTT might have been overlooked. During interview 8/17/22 at approximately 1:50 p.m., the API representative stated that the laboratory canceled their enrollment for PT and PTT for the 3rd event of 2021 on 7/26/21. She stated that the reason for cancellation was that the laboratory was no longer performing patient tests. She verified that the laboratory was not enrolled for 2022.

D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 API proficiency testing records and interview with GS 8/16/22, the laboratory failed to document evaluation of all ungraded and unacceptable proficiency testing results. Findings: Review of 2020, 2021, and 2022 API proficiency testing records revealed: 1. 2021 Hematology /Coagulation 1st event - no evaluation of the ungraded educational blood cell identification sample ECI-03. 2. 2021 Hematology/Coagulation 2nd event - no evaluation of the ungraded educational blood cell identification sample ECI-07. 3. 2021 Hematology/Coagulation 3rd event - no evaluation of the ungraded educational blood cell identification sample ECI-15 and the ungraded potassium hydroxide (KOH) sample VKP-03. During interview at approximately 11:00 a.m., the GS confirmed that there was no documentation of evaluation of the ungraded proficiency testing results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2020, 2021, and 2022 hematology maintenance logs 8/16/22, the laboratory failed to document maintenance as required for the Sysmex XT-2000i hematology analyzer for a period of approximately 10 months, October of 2021 thru August of 2022. Findings: Review of manufacturer's instructions revealed daily, weekly and "Other Maintenance". "Other Maintenance" includes "Clean Sample Rotor Valve" at 15,000 cycles. Review of 2020, 2021 and 2022 hematology maintenance logs revealed no documentation of "Clean Sample Rotor Valve" from October 2021 thru August of 2022. This deficiency was previously cited on 4/9/19.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedure and review of hematology calibration records 8/16/22, the laboratory failed to ensure calibration of the Sysmex XT - 2000i hematology analyzer was performed every 6 months as required. Findings: Review of laboratory hematology procedure "Sysmex XT-2000i Hematology Analyzer" revealed "Calibration and Precision", "Initial calibration is performed during installation by the Sysmex Field Service Representative. The field service rep performs calibrations every 6 months and emails printouts for the lab to keep....The laboratory must verify calibration every six months...". Review of Sysmex XT-2000i calibration records revealed a calibration was performed August 2020 with a expiration date February 2021. The next calibration was not performed until June 2021, 4 months after the previous calibration expired.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of coagulation records, and review of patient test report 8/16/22, the laboratory director (LD) failed to ensure the procedure for innovin lot number (#) changes included the specific criteria used by the pathologist to determine if PT/PTT normal ranges should be revised, failed to ensure PT/PTT "Normal Range Study" calculations for the current innovin lot # change were correct and failed to ensure the international normalized ratio (INR) calculation results were validated when the current innovin lot # was changed. 1. The LD failed to ensure the procedure for innovin lot # changes included the specific criteria used by the pathologist to determine if PT/PTT reference ranges would need to be revised. Findings: Review of laboratory procedure "CHANGING REAGENT POOLS FOR COAGULATION" revealed "PURPOSE: When changing to a new pool of reagents and controls it is important to establish new patient normal ranges and therapeutic ranges, unassayed (pt and ptt) control ranges, complete correlation studies, and communicate impact to the physician and nurses. Patient Correlations are done to evaluate lot-to-lot differences in reagent sensitivity. If significant changes are observed in patient normal ranges and patient comparison studies are considered acceptable and not statistically significant, the medical director or designee communicates the changes to the medical staff....FINAL EVALUATION OF DATA:...If significant differences exist and the pathologist deems it necessary to notify the medical staff, this notification will include as a minimum:....". The procedure stated "significant changes" and "significant differences" but failed to

	define the criteria used to determine if the change or difference is "significant". 2. The LD failed to ensure the PT/PTT "Normal Range Study" calculations used for the current innovin lot # change were correct. Findings: Review of coagulation records revealed a new lot # of innovin, Lot #564507, was put into use on 8/12/22. Review of the "PT/PTT Normal Range Study" performed for the new lot # of innovin revealed: a. a mean of 10.0 and a 0.42 standard deviation (SD) with a new expected range for PT of 9.5-11.5 seconds b. a mean of 26.7 and a 1.92 SD with a new expected range for PTT of 27.4-30.2 seconds. Using the laboratory's values for mean and SD, the new expected range for PT would be 9.2-10.9 seconds, and the new expected range for PTT would be 22.9-30.5 seconds. The study was signed by the LD 8/2/22, indicating review and approval of the new ranges. Review of a random PT/PTT patient test report (MRN # 3379345) dated 8/16/22 revealed a PT reference range of 9.4-11.2 seconds and a PTT reference range of 22.5-31.3 seconds. The ranges on the patient test report had not been updated to reflect the new ranges. 3. The LD failed to ensure the calculated international normalized ratio (INR) results were validated when the current innovin lot # was changed. Review of coagulation records revealed a new lot # of innovin, Lot #564507, was put into use on 8/12/22. Review of laboratory procedure "CHANGING REAGENT POOLS FOR COAGULATION" revealed "Changes made day of LIVE:...Validate INR results on initial control samples.". Review of coagulation records revealed no documentation the calculated INR results were validated.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2020, 2021, and 2022 coagulation and quality assessment records 8/16/22, the laboratory director failed to ensure that the laboratory's quality assessment plan was effective to identify and correct problems identified during the survey in the specialty of hematology. Findings: Review of the laboratory's "Quality Management and Patient Safety Plan" revealed the plan did not include specific details describing how all aspects of the laboratory's preanalytic, analytic, and postanalytic systems are monitored. For example, the plan states on page 4 "... Laboratory External Quality Control The purpose of External Quality control is to assess the accuracy of each test method by comparing the performance of the analysis with an external quality control program, such as proficiency surveys, and/or manufacturer peer group quality control programs. Laboratory performance can be compared against the performance of laboratories with the same or similar methods analyzing identical specimens. The group consensus result is considered the 'true', or accurate value. The performance of the ... Laboratory is evaluated by how close reported quality control results compare with those of the mean opinion of the group (all laboratories reporting). The ... Laboratory is enrolled in the American Proficiency Institute's (API) competency testing program. It is also enrolled in the Biorad QCNet program to evaluate quality control material recovery against peer groups. ..." The plan did not describe how these tools would be used by the laboratory to identify and correct problems. Review of 2020, 2021, and 2022 laboratory records revealed the laboratory's quality assessment plan failed to identify the following problems identified during the survey: 1. The laboratory failed to enroll

	in proficiency testing for PT and PTT when patient testing resumed in October 2021 (see D2000). 2. The laboratory failed to document evaluation of all ungraded and unacceptable proficiency testing results (see D5211). 3. The laboratory failed to document maintenance as required for the Sysmex XT-2000i hematology analyzer (see D5429). 4. The laboratory failed to ensure calibration of the Sysmex XT - 2000i hematology analyzer was performed every 6 months as required (see D5439). 5. The laboratory failed to ensure the procedure for innovin lot number (#) changes included the specific criteria used by the pathologist to determine if PT and PTT normal ranges should be revised, failed to ensure PT/PTT "Normal Range Study" calculations for the current innovin lot # change were correct, and failed to ensure the INR calculation results were validated when the current innovin lot # was changed (see D6093).